[7590-01-P]

## **NUCLEAR REGULATORY COMMISSION**

10 CFR Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, and 72

[Docket Nos. PRM-50-107; NRC-2013-0077]

Requirement to Submit Complete and Accurate Information

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking; consideration in the rulemaking process.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) will consider in the rulemaking process the issues raised in a petition for rulemaking (PRM), PRM-50-107, submitted by James Lieberman (the petitioner). The petitioner requested that the NRC amend its regulations to require that all persons seeking NRC approvals provide the NRC with complete and accurate information. Current NRC regulations pertaining to completeness and accuracy of information apply only to NRC licensees and license applicants. The NRC has determined that the issues raised in the PRM have merit and are appropriate for consideration in the rulemaking process.

**DATES:** The docket for the petition for rulemaking, PRM-50-107, is closed on **[INSERT DATE OF PUBLICATION IN THE** *FEDERAL REGISTER*].

ADDRESSES: Please refer to Docket ID NRC-2013-0077 when contacting the NRC about the

availability of information for this petition. You can obtain publicly-available documents related to this petition by using any of the following methods:

- Federal Rulemaking Web Site: Go to <a href="http://www.regulations.gov">http://www.regulations.gov</a> and search for Docket ID NRC-2013-0077. Address questions about NRC dockets to Carol Gallagher, telephone: 301-415--3463; e-mail: <a href="mailto:Carol.Gallagher@nrc.gov">Carol.Gallagher@nrc.gov</a>. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- The NRC's Agencywide Documents Access and Management System

  (ADAMS): You may obtain publicly-available documents online in the ADAMS Public

  Documents collection at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to <a href="mailto:PDR.resource@nrc.gov">PDR.resource@nrc.gov</a>. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in Section V of this document, Availability of Documents.
- The NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jenny Tobin, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2328; e-mail: <a href="mailto:Jennifer.Tobin@nrc.gov">Jennifer.Tobin@nrc.gov</a>.

### **SUPPLEMENTARY INFORMATION:**

- I. Background.
- II. Requirement to Submit Complete and Accurate Information.
- III. Analysis of Public Comments.
- IV. Determination of Petition.
- V. Availability of Documents.

## I. Background.

On April 15, 2013, the NRC received a PRM (ADAMS Accession No. ML13113A443) requesting the NRC to revise its regulations relating to nuclear reactors at §§ 50.1, 50.9, 52.0, and 52.6 of Title 10 of the *Code of Federal Regulations* (10 CFR) to expand its "regulatory framework to make it a legal obligation for those non-licensees who seek NRC regulatory approvals be held to the same legal standards for the submittal of complete and accurate information as would a licensee or an applicant for a license." James Lieberman, a regulatory and nuclear safety consultant, submitted the petition which was filed on April 15, 2013, and later amended on September 16, 2013. The petitioner originally requested that the NRC amend its regulations in 10 CFR parts 50 and 52, to require all persons who seek NRC approvals to provide the NRC with complete and accurate information.

The NRC assigned the petition Docket Number PRM-50-107 and published a notice of receipt of the petition in the *Federal Register* (FR) on June 10, 2013 (78 FR 34604). The NRC requested public comment on the petition and received two comments, both supporting the petition. On September 16, 2013 (ADAMS Accession No. ML13113A443), the petitioner amended the rulemaking petition to expand its scope to include not only 10 CFR parts 50 and

52 for reactors, but the regulatory framework for radioactive materials, waste disposal, transportation, and spent fuel storage as well (10 CFR parts 30, 40, 60, 61, 63, 70, 71, and 72). The NRC published a notice regarding the amended petition (ADAMS Accession No. ML13261A190) in the *Federal Register* requesting comment (79 FR 3328; January 21, 2014). One additional comment in support of the amended petition was received.

The petitioner asserts that non-licensees (including vendors and other contractors) used by NRC-regulated entities to meet regulatory requirements should be subject to the same requirements for complete and accurate submissions as NRC licensees and license applicants. When the Commission promulgated the 1987 "Completeness and Accuracy of Information" rule (52 FR 49362; December 31, 1987) (the 1987 rule), neither the rule language nor the Statement of Considerations (SOC) discussed non-licensees submitting information to the NRC for regulatory approvals. The 1987 rule included nearly identical "Completeness and Accuracy of Information" requirements in 10 CFR parts 30, 40, 50, 60, 61, 70, 71, and 72. When the Commission added 10 CFR parts 52 and 63 to its regulations, it added "Completeness and Accuracy of Information" requirements to these parts as well (72 FR 49521, August 28, 2007; and 66 FR 55732, November 2, 2001; respectively). The petitioner asserts that the intent of this petition is to close the gap that exists in NRC requirements between licensees/applicants and non-licensees regarding the submittal of complete and accurate information for NRC approval.

The NRC assigned the petition Docket Number PRM-50-107 and published a notice of receipt of the petition in the *Federal Register* (FR) on June 10, 2013 (78 FR 34604). The NRC requested public comment on the petition and received two comments, both supporting the petition. On September 16, 2013 (ADAMS Accession No. ML13113A443), the petitioner amended the rulemaking petition to expand its request to include not only 10 CFR parts 50 and 52 for reactors, but the regulatory framework for radioactive materials, waste disposal, transportation, and spent fuel storage as well (10 CFR parts 30, 40, 60, 61, 63, 70, 71, and 72).

In the amended petition, the petitioner also requested that the "scope" section for each of the parts be revised to add language to highlight that any person seeking or obtaining an NRC approval for a regulated activity would be subject to enforcement action for violation of the completeness and accuracy provision of that part. The applicable sections are §§ 30.1, 40.2, 50.1, 52.0, 60.1, 61.1, 63.1, 70.2, 71.0, and 72.2.

# II. Requirement to Submit Complete and Accurate Information.

The NRC's regulations at 10 CFR 30.9, 40.9, 50.9, 52.6, 60.10, 61.9a, 63.10, 70.9, 71.7, and 72.11 implemented: 1) The longstanding policy that license applicants and licensees provide the Commission information that is complete and accurate in all material respects and maintain such information as required; and 2) the requirement that license applicants and licensees notify the NRC of any information they identify as having, for the regulated activity, a significant implication for the public health and safety or common defense and security.

The 1987 rule re-emphasized the NRC's need to receive complete and accurate information and timely notification of safety significant information from its licensees and license applicants if the NRC is to fulfill its statutory responsibilities under the Atomic Energy Act of 1954, as amended (AEA). The SOC for the 1987 rule stated that "the accuracy and forthrightness in communications to the NRC by licensees and applicants for licenses are essential if the NRC is to fulfill its responsibilities to ensure that utilization of radioactive material and the operation of nuclear facilities are consistent with the health and safety of the public and the common defense and security." The SOC relied on the general authority provision in AEA Section 161b. that permits the NRC to establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material. The SOC also specifically mentioned the importance of accurate

information in AEA Section 186, which authorizes the NRC to revoke any license for material false statement in an application or statement of fact required under AEA Section 182.

However, similar concerns also are raised when non-licensees seek the NRC's approval in other situations. For example, a non-licensee may submit a description of its Quality

Assurance (QA) program to the NRC for approval in support of a Certificate of Compliance

(CoC) for transportation and storage casks. The regulations at 10 CFR part 71 and

part 72 set forth requirements for QA programs in subparts H and G, respectively.

Non-licensees who intend to apply for a CoC establish, maintain, and execute programs satisfying the QA requirements for the control of quality-affecting activities such as design, procurement, special processes, inspection, and testing, among other activities. Implementing an effective QA program during transportation or storage cask design and testing pre-application phases provides adequate confidence that the systems or components will perform satisfactorily in service.

On more than one occasion the NRC has received from a non-licensee a description of a QA program for NRC approval in accordance with 10 CFR parts 71 and 72 requirements. After reviewing this information, the NRC staff approved the QA program, as documented. However, a subsequent on-site inspection of that NRC-approved QA program resulted in a finding of inadequate implementation of certain quality-related activities. Had this QA program implementation deficiency gone unidentified and uncorrected, it could have resulted in design issues or reduced confidence that systems or components would perform satisfactorily in service. Under current regulations, the NRC can only take an enforcement action against the applicant if the cause of a QA program deficiency is attributable to an applicant providing incomplete or inaccurate information. The NRC is unable to take enforcement action against the non-licensee for not providing complete and accurate information that was submitted for

NRC's approval; the NRC is limited to issuing an administrative action, such as a notice of

nonconformance.

A topical report is another example of one type of information submitted to the NRC by

non-licensees for regulatory approval. Once reviewed and approved, the NRC endorses the

use of the topical report, and licensees implement the report accordingly. The petitioner cited

reactor topical reports as an example of a single safety evaluation report, once approved by the

NRC, that may be adopted by many licensees, and therefore greatly magnify the impact of any

error beyond the non-licensee applicant for the topical report itself.

The petition states that non-licensees who submit information to the NRC for approval

should be held accountable for providing complete and accurate information. The petitioner's

proposed rule change would provide the NRC staff with additional enforcement tools to

encourage non-licensees to submit complete and accurate information to the NRC.

III. Analysis of Public Comments.

The NRC received a total of three comment submissions on the petition and amended

petition from two private citizens. The NRC received two public comments in response to the

June 10, 2013, Federal Register notice. Both were in support of the petition, one suggested the

inclusion of additional licensees in the petition. In response to the January 21, 2014, Federal

Register notice, the NRC received a second comment from a previous commenter reiterating

his support on the amended petition.

Comment No. 1:

Commenter: Hugh Thompson, Talisman International

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Comment: The commenter asserted that the NRC should consider for rulemaking Mr.

Lieberman's petition to require vendors and suppliers to provide complete and accurate

information. The commenter also stated that the NRC should consider expanding the original

petition's request to include other parts of the regulations that have the same completeness and

accuracy provisions, namely 10 CFR parts 30, 40, 61, 70, 71, and 72. The commenter

highlighted that it is important to have complete and accurate information in submittals by

non-licensees who seek the following: 1) Exemption from NRC regulations; and 2) NRC

approval that their activities do not need a license. The commenter pointed out that currently

there is no legal obligation for a vendor to provide complete and accurate information either in

the application for a topical report or in response to NRC questions on the topical report. The

commenter noted that this oversight has been brought to light during litigation.

NRC Response: The NRC agrees with this comment, and intends to consider this issue

in the rulemaking process. In addition, the petitioner amended the petition to expand the

request of proposed changes in the regulations.

Comment No. 2:

Commenter: Charles Haughney

Comment: The commenter stated that the NRC should consider Mr. Lieberman's

petition for rulemaking.

NRC Response: The NRC agrees with the comment and intends to consider this PRM

in the rulemaking process.

Comment No. 3:

Commenter: Hugh Thompson, Talisman International

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Comment: The commenter stated that the NRC should consider for rulemaking the revised petition that expands the original petition request.

NRC Response: The NRC agrees with the comment and intends to consider the PRM in the rulemaking process.

### IV. Determination of Petition.

Non-licensee applicants for NRC regulatory approvals (e.g. topical report, an exemption from licensing, or submission of a QA program) currently are not under the same regulatory obligation as licensees or license applicants to provide complete and accurate information. Non-licensees that have received an NRC approval are also not under the same regulatory obligation as licensees to notify the NRC of any information that may have a significant implication for public health and safety or the common defense and security. As a result, the lack of similar requirements for non-licensees could adversely affect public health and safety or the common defense and security. As with licensees and license applicants, the NRC staff relies on the information submitted by non-licensees as the primary basis for approving their requests; it is fundamental for good regulation that all applicants for NRC approvals meet the same requirement to submit complete and accurate information. It is also important that both licensees and non-licensees operating under an NRC approval be required to notify the NRC of information they have identified as having a significant implication for the public health and safety or common defense and security. In the case of reactor topical reports, as cited by the petitioner, a single safety evaluation report may be adopted by many licensees once it has been approved by the NRC, greatly magnifying the impact of any errors beyond the non-licensee applicant for the topical report itself.

The NRC agrees with the petitioner that non-licensee applicants for NRC approvals in all subject areas (e.g. reactors, materials, transportation, and waste) should be required to submit complete and accurate information. Imposing the same requirement for completeness and accuracy of information to all non-licensee applicants for NRC approvals ensures a consistent and comprehensive set of regulatory expectations.

Although not mentioned in the petition or the amended petition, the NRC staff identified other portions of the regulations that contain similar requirements for "Completeness and Accuracy of Information." As a result, the NRC also considered the applicability of the issue to 10 CFR parts 54, 76, and 110 in its evaluation.

For these reasons, the NRC will consider the issues raised in the petition in the rulemaking process.

# V. Availability of Documents.

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated. For information on accessing ADAMS, see the ADDRESSES section of this document.

Date	Document	ADAMS Accession Number/Federal Register Citation
April 15, 2013	Original Petition (PRM-50-107)	ML13113A443
June 10, 2013	Original FRN	78 FR 34604
September 16, 2013	Amended Petition	ML13261A190
January 21, 2014	Amended FRN	79 FR 3328
August 29, 2013	Comment 1: Hugh Thompson	ML13241A222
August 26, 2013	Comment 2: Charles Haughney	ML13246A383
April 10, 2014	Comment 3: Hugh Thompson	ML14100A198

Dated at Rockville, Maryland, this 20th day of February, 2015.

For the Nuclear Regulatory Commission.

Mark A. Satorius, Executive Director for Operations.

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